

Late removal of retrievable caval filters

Ludwig K von Segesser, Enrico Ferrari, Piergiorgio Tozzi, Saad Abdel-Sayed, Denis Berdajs

Cardio-Vascular Research, Department of Surgery and Anaesthesiology, Lausanne, Switzerland

Summary

The advent of retrievable caval filters was a game changer in the sense, that the previously irreversible act of implanting a medical device into the main venous blood stream of the body requiring careful evaluation of the pros and cons prior to execution suddenly became a “reversible” procedure where potential hazards in the late future of the patient lost most of their weight at the time of decision making. This review was designed to assess the rate of success with late retrieval of so called retrievable caval filters in order to get some indication about reasonable implant duration with respect to relatively “easy” implant removal with conventional means, i.e., catheters, hooks and lassos. A PubMed search (www.pubmed.gov) was performed with the search term „cava filter retrieval after 30 days clinical“, and 20 reports between 1994 and 2013 dealing with late retrieval of caval filters were identified, covering approximately 7,000 devices with 600 removed filters. The maximal duration of implant reported is 2,599 days and the maximal implant duration of removed filters is also 2,599 days. The maximal duration reported with standard retrieval techniques, i.e., catheter, hook and/or lasso, is 475 days, whereas for the retrievals after this period more sophisticated techniques including lasers, etc. were required. The maximal implant duration for series with 100% retrieval accounts for 84 days, which is equivalent to 12 weeks or almost 3 months. We conclude that retrievable caval filters often become permanent despite the initial decision of temporary use. However, such “forgotten” retrievable devices can still be removed with a great chance of success up to three months after implantation. Conventional percutaneous removal techniques may be sufficient up to sixteen months after implantation whereas more sophisticated catheter techniques have been shown to be successful up to 83 months or more than seven years of implant duration. Tilting, migrating, or misplaced devices should be removed early on, and replaced if indicated with a device which is both, efficient and retrievable.

Key words: *Caval filters; retrievable; convertible; permanent; pulmonary emboli; thrombo-embolic disease*

Introduction

The main indications for implantation of a caval filter (fig. 1) in the presence of proven venous thrombo-emboli include A) recurrent pulmonary emboli despite efficient anticoagulation B) contra-indication of anticoagulation in the presence of pulmonary emboli C) complication of anticoagulation D) inability to achieve or maintain adequate anticoagulation [1]. However, the indications are only part of the parameters of the equation about the usefulness of caval filtration in a specific patient. As a matter of fact, and based on our own experience, there are also a number of concerns related to the caval filters themselves including filter dislodgement, filter penetration, filter fracture, venous thrombo-embolic events originating from the caval fil-

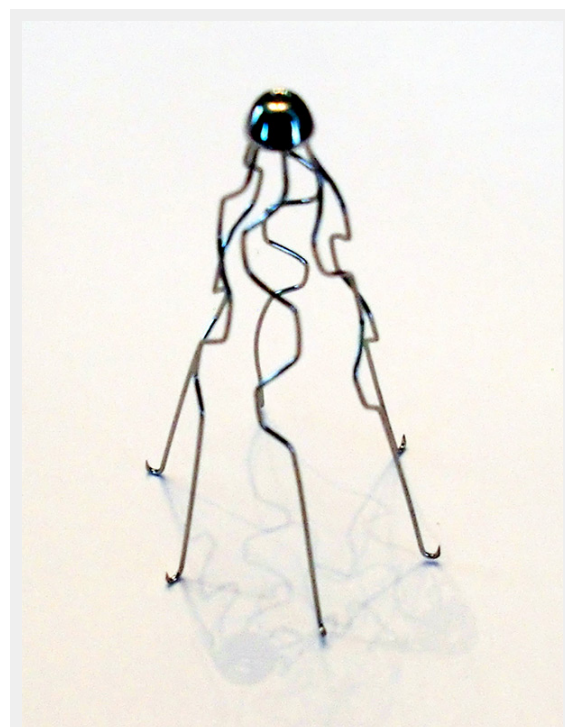


Figure 1

Original Greenfield vena cava filter (catalog no. 2846). This device was designed for permanent implantation including sharp hooks at the bottom to prevent migration. In contrast, retrievable caval filters have a hook or a graspable area at the tip that allows for traction and refolding into a sheath.

ter, complete thrombosis of the vena cava related to the caval filter, etc. Hence, the advent of retrievable caval filters in the sixties of the last century [2] was a game changer in the sense, that the previously irreversible act of implanting a medical device into the main venous blood stream of the body requiring careful evaluation of the pros and cons prior to execution suddenly became a “reversible” procedure where potential hazards in the late future of the patient lost most of their weight at the time of decision making. This does not mean that late problems related to caval filters vanished [3, 4]. As a matter of fact it turned out in our clinical practice that so-called retrievable caval filters typically designed and approved for use for two or three weeks (less than 30 days) were often left in situ and thus became permanent. It is only at the occasion of complications or new health problems that the retrieval of the originally temporary caval filter was reconsidered, and sometimes attempted. The present review was designed to assess the rate of success with late retrieval of so called retrievable caval filters in order to get some indication about reasonable implant duration with respect to relatively “easy” implant removal with conventional means, i.e., catheters, hooks and lassos.

Search strategy

In order to assess the rate of success with late retrieval of temporary caval filters, a PubMed search (www.pubmed.gov) was performed on 13 October 2013, with the search term “cava filter retrieval after 30 days clinical”. This search term was based on the rationale that the most frequent venous filter deployment site is the inferior vena cava, that the retrievable caval filters are typically designed for an implant duration of 15 ± 10 days, and that the 30 days implant interval is a regulatory hurdle with less stringent criteria for medical devices designed for less than 30 days implant duration.

Results

The search described above identified 20 reports between 1994 and 2013 dealing with late retrieval of caval filters.

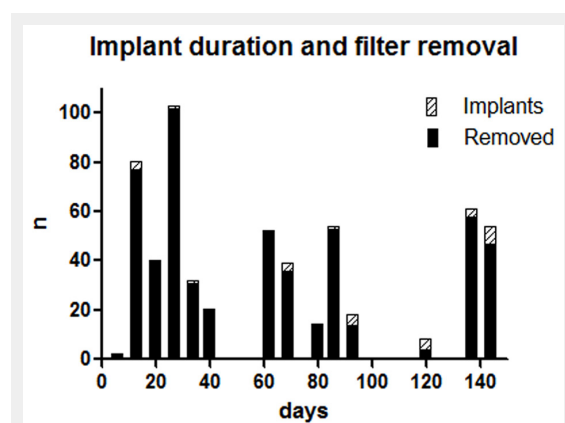


Figure 2

Proportion of filters removed over time. It is interesting to note, that up to 84 days, 100% filter removal can be obtained by conventional means (hooks and lassos).

The 15 reports providing sufficiently detailed information about the number of implants, the filter position, the mean and/or range of implant duration, the proportion of successfully removed filters, and the number of not removed filters with the reason for failure if available are shown in table 1. This compilation covers approximately 7,000 devices. The total number of removed filters in table 1 accounts for 600 devices. The maximal duration of implant reported is 2,599 days and the maximal implant duration of removed filters is also 2,599 days. The maximal duration reported with standard retrieval techniques, i.e., catheter, hook and/or lasso, is 475 days, whereas for the retrievals after this period more sophisticated techniques including lasers etc. were required. The key problem in failure to remove retrievable caval filters appears to be the position of the filter tip or key filter part designed for re-folding the device. We can tell from our experience, that tips of tilted filters tend to sink into the caval wall and can become overgrown, thus making capture difficult. The maximal implant duration for series with 100% retrieval (fig. 2) accounts for 84 days, which is equivalent to 12 weeks or almost 3 months (table 2).

In our experience, there are many good reasons for postponing early removal of retrievable caval filters including patent foramen ovale and/or other intra-cardiac right to left shunts, presence of clot within the caval filter at the time of planned removal, unresolved deep vein thrombosis, persistent pulmonary hypertension, persistent respiratory insufficiency, unstable anticoagulation and others.

Discussion

The most striking finding of this review is the fact, that retrievable caval filters designed for temporary caval filtration of two or three weeks (less than 30 days) have been successfully removed in all cases where this was attempted, in several series [6, 7, 11, 13, 14] as many as 12 weeks after insertion. This includes Celect, Bard, Gunther, Tempo and other filter brands. Although this does not mean that the caval filters designed for short term use should be implanted routinely for long term use, it is extremely helpful for clinical practice to know, that the regulatory threshold of 30 days for temporary caval filtration by the means of a retrievable caval filter is not written in stone for clinical reasons. There can be no doubt, that temporary caval filtration of three weeks which may be extended to almost three months without compromising the rate of removal reduces the pressure of too early a removal of the intra-caval device, when this may still be required, or the removal process is contra-indicated at a specific moment for some other reason [20], provided that the device considered is designed for longer term use or later conversion to a non-filtering device.

Interestingly enough, there are other devices, that are left in the vena cava for some time and are therefore designed to be removed sooner or later, like intravascular gas exchangers [21] built for temporary extra-pulmonary gas transfer, which can be removed by simple traction after more than 28 days [22], venous cannulas used for extracorporeal membrane oxygenation including collapsible designs, which can also be removed by simple traction after

as many as 28 days [23–25]. In contrast, permanent implants in the vena cava like catheters connected to valves or ports, pace maker leads, as well as defibrillator leads can become very difficult for late removal in toto and may require special expertise as well as specific instrumentation including lasers, threaded stylets, cutting sheaths, etc.

These more complex removal procedures bring us to the second important finding of this review. As a matter of fact, even caval filters implanted for 2,599 days can be removed without open surgery but with specific trans-luminal techniques after this period of indwelling, whereas standard retrieval techniques may still work after an implant duration of up to 475 days (table 2).

There are a number of additional observations listed in table 1 which deserve to be highlighted. The review of Angel LF covered 6,834 implants of multiple brands, but did not reveal a markedly superior design. Two reports with smaller series mentioned strut fractures [6, 15]. The latter can migrate and may require surgical removal under certain circumstances. One key reason for problems with the removal of retrievable caval filters appears to be the position of the filter tip or key filter part designed for re-folding the device. The latter can be difficult to capture if it adheres to the venous wall [10] a situation which is favoured if the filter is tilted with reference to the caval axis. In such a situation the point of traction designed for capture by the retrieval device (typically a hook) may be flush to the caval wall, or even hidden in intramural fashion. With a tilted device, even the approach with a lasso from the other side, may be difficult or impossible and therefore it may not be

possible to be snared and reloaded into a sheath. It is a fact that stent arms and arches driven by excessive expansion force (e.g., due to expansion in tilted position) lead to more media atrophy with intimal overgrowth [25], can penetrate the basal membrane of the endothelium, and the adventitia, and thus it can be impossible to grab the specific point of traction designed for device refolding prior to re-loading into a catheter. Hence, the indication to consider earlier retrieval of tilted retrievable caval filters where overgrowth of the key components designed for device collapsing are risking success with standard retrieval techniques, and to avoid more complex interventions including open surgery. We conclude that retrievable caval filters often become permanent. However, such "forgotten" retrievable devices can still be removed by conventional catheter techniques with a great chance of success up to three months after implantation. Conventional percutaneous removal techniques may be sufficient up to sixteen months after implantation whereas more sophisticated catheter techniques have been shown to be successful up to 83 months or more than seven years of implant duration. Tilting, migrating, or misplaced devices should be removed early on, and replaced if indicated with a device which is both, efficient and retrievable. Our preference goes for retrievable or convertible temporary caval filters designed for optional permanent implantation.

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Table 1: Main findings for duration and success of removal with various filter types.

Reference	Year published	Author	Filter brand	No. devices	Position	Duration Mean	Range	Removed	Not removed
						days		days	cause
5	2013	Smouse HB	Crux	54	Cava	84.6 ± 57.6	6–190	53/54	1 remained
6	2013	Kuo WT	X	50	Cava	815		20–2599 50/50	fractures > 1y
7	2011	Van Ha TG	X	20	Iliac	40±10	30–71	all	none
8	2011	Angel LF	X	6,834	Cava	NA		NA	no superior design
9	2010	Johnson MS	Option	39	Cava	67	1–175	36/39	3 remained
10	2009	Binkert CA	G2	61	Cava	140	5–300	58/61	3 tip at wall
11	2009	Sangwaiya MJ	Celect	14	Cava	84	6–190	14/14	none
12	2007	Yamagami T	Gunther	80	Cava	13.4 ± 4.2	NA	77/80	3 remained
13	2007	Piano G	Bard/Gu	52	Cava	63 ± 30	NA	52/52	8 refused
14	2006	Bovino G	Tempo	103	Cava	29.5 ± 14	2–86	102/103	none <84 d
15	2006	Stefanidis D	X	54	Cava	142	17–475	47/54	1 strut fracture
16	2006	De Gregorio M	Gunther	32	Cava	30	NA	31/32	1 force > 9.8N
17	2005	Rosenthal D	OptEase	40	Cava	16.4 ± 7.2	3–48	40/40	none
18	2005	Imberti D	ALN	18	Cava	<3 months		14/18	
				8	Cava	>3 months		4/8	
19	1994	Nakagawa	Nitinol	2	Cava	6	5–7	2/2	none

Table 2: Main findings.

Number of reports	15 reports
Period of reports	1994 and 2013
Number of devices covered	7,000 devices
Total number of removed filters	600 devices
Maximal implant duration	2,599 days
Maximal implant duration of removed filters	2,599 days
Maximal implant duration with standard retrieval	475 days
Maximal implant duration with 100% retrieval	84 days = 12 weeks <3 months

Correspondence: Professor Ludwig K. von Segesser, MD, FETCS, FACS, FESC, Cardio-Vascular Research, Department of Surgery and Anaesthesiology, CHUV, BH 05–105, Rue du Bugnon 46, CH-1011 Lausanne, Switzerland, [LK\[at\]Segesser.com](mailto:LK[at]Segesser.com)

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Figures (large format)

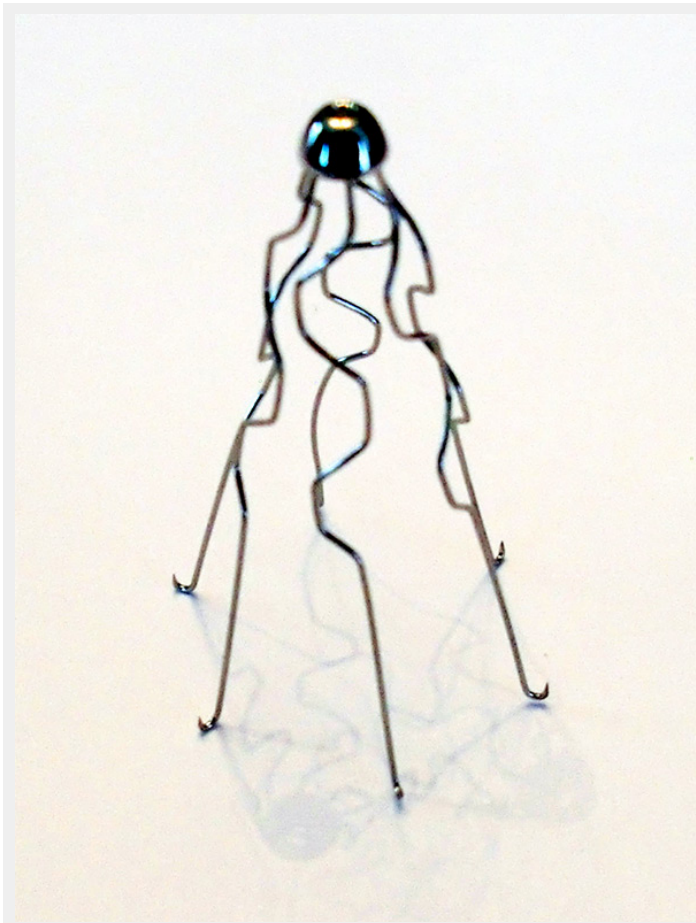


Figure 1

Original Greenfield vena cava filter (catalog no. 2846). This device was designed for permanent implantation including sharp hooks at the bottom to prevent migration. In contrast, retrievable caval filters have a hook or a graspable area at the tip that allows for traction and refolding into a sheath.

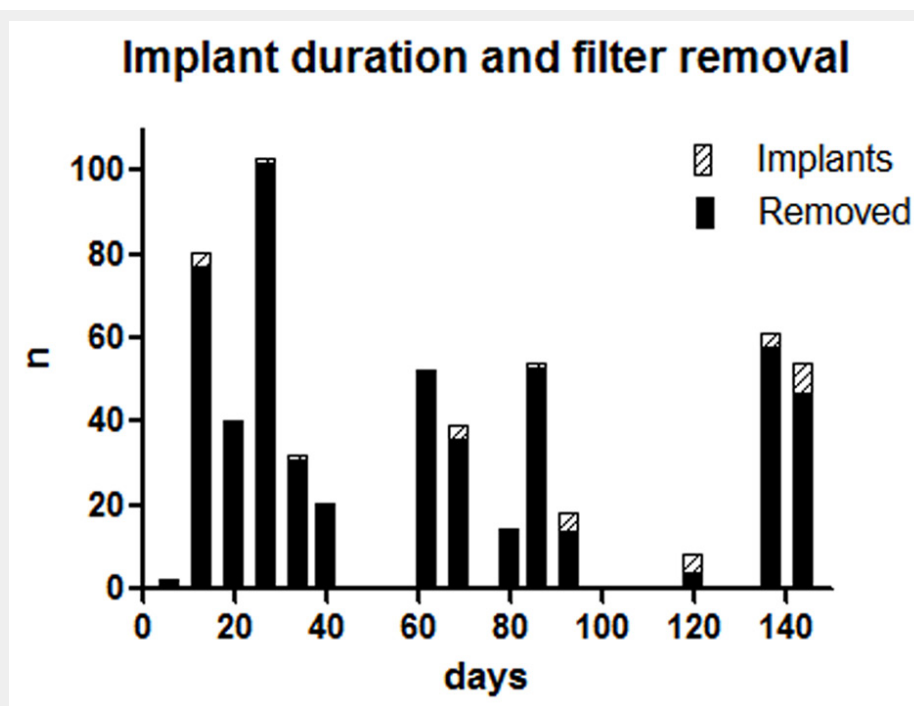


Figure 2

Proportion of filters removed over time. It is interesting to note, that up to 84 days, 100% filter removal can be obtained by conventional means (hooks and lassos).